The Commonwealth of Massachusetts
Executive Office of Energy and Environmental Affairs
100 Cambridge Street, Suite 900
Boston, MA 02114

Deval L. Patrick
GOVERNOR

Timothy P. Murray
LIEUTENANT GOVERNOR

Ian A. Bowles
SECRETARY

Tel: (617) 626-1000
Fax: (617) 626-1181
http://www.mass.gov/envir

RESPONSE TO COMMENTS ON PROPOSED AMENDMENTS TO 301 CMR 40.00 TOXICS USE FEE AND 301 CMR 41.00 TOXIC OR HAZARDOUS SUBSTANCE LIST

Regulatory Authority:
M.G.L. Chapter 21I

December 2007

SUMMARY

In October 2007, the Executive Office of Energy and Environmental Affairs (EOEEA) proposed revisions to 301 CMR 40.00 *Toxics Use Fee* and 301 CMR 41.00 *Toxic or Hazardous Substance List* and made available supporting documents describing the proposed regulatory revisions.

The revisions to 301 CMR 40.00 and 301 CMR 41.00 are designed to implement statutory amendments to the Toxics Use Reduction Act (TURA, M.G.L. Chapter 21I) that were signed into law in July 2006. These regulatory revisions implement new reporting provisions that affect calendar year 2008 toxics use reports that are due by July 1, 2009.

EOEEA held a public hearing and solicited public comments on the proposed revisions in accordance with M.G.L. Chapter 30A. EOEEA published notice of the public hearing and comment period on November 9, 2007 in the Springfield Republican, Worcester Telegram and Gazette, and the Boston Globe, and notified interested parties via electronic mail of the public hearing and comment period. The public hearing was held on November 30, 2007, at 100 Cambridge Street, 2nd floor Conference D, Boston and written comments were accepted until the end of the day Friday, November 30, 2007.

EOEEA did not receive any oral or written testimony at the public hearing, but did receive three sets of written comments during the public comment period. These comments are summarized below, along with EOEEA's response to each comment. EOEEA did not make any changes to the final regulation revisions based on public comments. The following people/organizations submitted comments:

Sandra Wyman – Sandra Wyman Associates
Armin Steiner – Massachusetts Chemistry and Technology Alliance, Inc.
Steve Risotto – Halogenated Solvents Industry Alliance, Inc.

COMMENTS AND RESPONSES

DEFINITIONS

1. Comment: The definition for Manufacture in 301 CMR 40.02 and 301 CMR 41.02 is too broad. We recommend replacement of the proposed wording with the following definition in 301 CMR 40.02 and 41.02:

> Manufacture means to produce, prepare, import or compound a toxic or hazardous substance. Manufacture shall also mean to produce a toxic or hazardous substance ~~coincidentally~~ as a byproduct resulting from a known or anticipated side reaction during the manufacture, processing, ~~use~~ or disposal ~~of~~ in conjunction with another substance or mixture of substances, including a toxic substance that is separated from such other substance or mixture of substances as a byproduct, ~~and a toxic substance that remains in such other substance or mixture of substances as an impurity~~.

Response: The term manufacture is defined in the TURA statute (M.G.L. Chapter 21I), therefore, the TURA statute would need to be amended in order to change the definition. EOEEA will maintain the definition as proposed, making it consistent with the statute and the current definition in MassDEP regulations 310 CMR 50.00 *Toxics Use Reduction*.

HIGHER AND LOWER HAZARD SUBSTANCE DESIGNATION

1. **Comment:** The practical interpretation of M.G.L. 21I: Section 9 (D) meant that for each number of toxic hazardous substances that were declared higher hazard substances, an equal number of toxic hazardous substances would be declared lower hazard substances.

Response: There is no language in Section 9D to support the commenter's interpretation that an equal number of higher and lower hazard substances must be designated each year by the Council. While no lower hazard substance recommendations were brought before the Council during calendar year 2007, it is likely there will be in calendar year 2008.

2. Comment: The TURA amendments provide no objective criteria for selection of higher hazard substances and the Board has provided no evidence that any such criteria were applied to its current selection of the 11 candidate substances or to its previous list of more hazardous substances.

Response: Higher hazard substances are selected using an expert judgment method adapted from the Delphi Method, a well-developed technique for reaching consensus among experts. The term Delphi Method came from a study concerning the use of expert opinion called Project Delphi performed by the Rand Corporation in the 1950s for the U.S. Air Force. This study aimed to "obtain the most reliable consensus of opinion of a

group of experts." The Delphi method is appropriate when accurate information is unavailable or expensive to obtain or evaluation models require subjective inputs to the point where they become the dominating parameters. Additional information is available in the following report: "Categorization of the Toxics Use Reduction List of Toxic and Hazardous Substances," TURI Methods and Policy Report No. 18, 1999.

The Science Advisory Board considered many different algorithms for their initial categorization of the TURA chemical list, but found all of them lacking, particularly in the way they handled issues of uncertainty and missing data. An expert judgment method had been used by Polaroid Corporation to develop their groundbreaking chemical ranking system, and was determined by the Board to be a more satisfactory approach to evaluate and develop a consensus than the algorithm methods.

In addition, the Science Advisory Board's methods were discussed during meetings of stakeholders convened to advise the Legislature on the 2006 TURA Amendments. There was general support from those stakeholders for continuing to use the expert judgment method to implement the 2006 Amendments.

Screening endpoints are used as a framework for the Science Advisory Board deliberations. For all deliberations regarding the chemical list and categorization of the list, objective scientific hazard data are gathered for the substances in question. Data points are discussed in the following four major areas: human health, environmental, safety, and persistence/bioaccumulation.

For categorization of the full EPCRA list, the Board discussed and chose the following eight screening endpoints:

- Carcinogenicity (IARC Classification)
- Oral LD50
- Reference dose (RFD)
- Threshold limit value (TLV) and/or permissible exposure limit (PEL)
- Aquatic LC50
- Flash point (FP)
- pH (used pKa and pKb)
- Bioconcentration factor (BCF)

In addition, the Board asked that the following endpoints be added prior to choosing the first 10 Higher Hazard Substances:

- Persistence, Bioaccumulation, and Toxicity values (PBT)
- Mutagenicity
- Developmental Toxicity
- Neurotoxicity
- Reproductive Toxicity
- Minimum Risk Levels (MRLs)

These endpoints were considered using the expert judgment method for each chemical. Each chemical was considered for its overall potential impact, not only for a particular endpoint. For that reason, for example, the 11 recommended chemicals are not necessarily the ones with the highest carcinogenicity or toxicity values. The recommended chemicals are the ones that the Board members, using expert judgment and the listed data, considered to be the best candidates for higher hazard designation based on their inherent toxicity and safety hazards. It is important to note that the Board was not charged with looking at issues beyond safety/toxicity, such as quantities used in the Commonwealth and/or exposure potential. TURI, in its policy analysis, considered issues regarding the use of the chemicals before making its recommendations to the Administrative Council.

3. Comment: Although our comments are specifically directed at the proposed designation for trichloroethylene, they reflect a more general concern with the process that led to its selection. Before designating any substances as higher hazard, [the commenter] urges the Administrative Council to develop a more formal selection process that addresses both hazard and risk and that focuses the state's limited resources on those efforts that can provide the greatest potential public health benefit.

Response: The TURA statute does not require the evaluation of risk or exposure as criteria for recommending or designating chemicals as higher hazard substances. Section 9 D of Chapter 21I states that "The council shall designate substances as a higher hazard substance, a lower hazard substance or may leave any substance as an otherwise uncategorized toxic or hazardous substance in consultation with the institute and the board." The statute then directs the Council to "first consider designating as a higher hazard substance those substances designated as Category 1/more hazardous by the board." Trichloroethylene (TCE) is one of the chemicals on the Category 1/more hazardous list created by the deliberations of the Science Advisory Board.

The institute prepared a policy analysis for TCE that included a summary of the state of the science and an explanation of feasible options and alternatives for the most significant industrial uses of the chemical in Massachusetts. The analysis identifies many technically feasible and cost effective toxics use reduction options for companies using TCE in cleaning applications and formulating paints and adhesives. The policy analysis highlights the TURA program's significant experience in helping companies identify and implement alternatives through the Institute's Surface Solutions Laboratory and the Office of Technical Assistance's business assistance program. In addition to the strong supporting science, the TURA program's significant experience and expertise in helping companies identify and implement suitable alternatives to TCE was a significant driver for the Institute's recommendation, and the Council's designation of TCE as a higher hazard substance.

4. **Comment:** The implications of the designation of a substance as higher hazard under TURA demand that the selection process be transparent and based on objective criteria.

Response: All meetings of the Science Advisory Board, the Advisory Committee to the Administrative Council, and the Administrative Council are announced and open to the public. Designation by the Administrative Council of a substance as a higher or lower hazard substance does not take regulatory effect until it is codified in 301 CMR 41.00. Changes to 301 CMR 41.00 are subject to the MGL c. 30A public hearing process, where interested parties can provide comment prior to the designation becoming effective. Regarding the use of objective criteria, please see the response to comment # 2.

5. Comment: The suggestion of genotoxic, immunotoxic, and teratogenic effects of trichloroethylene in the support document prepared by TURI staff, moreover, is not supported by the available evidence. [The commenter] recently completed developmental and immunotoxicity studies for trichloroethylene as part of a voluntary agreement with the Agency for Toxic Substances and Disease Registry (ATSDR). These studies observed no evidence of developmental effects in laboratory rats and evidence of immune suppression only at the highest dose (1,000 ppm).

Response: The SAB used what it considered to be the best available data for TCE during their deliberations. The commenter did not provide data from the study they cite; therefore, no comparison can be performed to corroborate the commenter's assertion.

6. Comment: Facilities using trichloroethylene have been subject for many years to a comprehensive set of federal, state, and often, local requirements to ensure that waste containing the solvent is properly handled, stored, transported, processed, and destroyed. The proposed designation of trichloroethylene as a higher hazard substance under TURA will have little, if any, impact on improving waste practices at the affected facilities and will have absolutely no impact on existing soil and groundwater contamination. Since neither the hazard nor the risk presented by trichloroethylene support its selection as a higher hazard substance, [the commenter] opposes the proposal to designate it as such.

Response: EOEEA agrees with the commenter that trichloroethylene is subject to many state and federal regulations, including the Massachusetts TURA regulations. EOEEA also agrees that the designation of TCE as a higher hazard substance will have no impact on improving existing soil and groundwater contamination. However, such designation may result in more businesses seeking to eliminate their use of TCE, thereby reducing potential worker exposure to TCE and potentially preventing future releases of TCE to the environment.

EOEEA believes that companies subject to TURA's materials tracking and accounting through TUR reporting and planning will be better informed about the costs and opportunities for improving the overall management of the chemcials they use. The TURA process informs business decisions about a company's chemical use, generally resulting in a reduction in the use, handling, exposure, release, waste management, and disposal of hazardous substances. The TURA data confirm that significant reductions have been achieved in TCE use, waste generation, and releases to the environment by those companies subject to the requirements of TURA reporting and planning.

TOXIC USE REDUCTION PLANNER (TURP) RECERTIFICATION CREDITS

1. Comment: One commenter stated that recertification requirements should be the same for general practice toxic use reduction planners as they are for limited practice planners. They also expressed concern that resource conservation plan recertification requirements are unnecessarily complicated. And lastly, they proposed changes in certification requirements for Environmental Management Systems (EMS) professionals and TUR planners.

Response: Certification and recertification requirements for EMS Professionals, Toxic Use Reduction Planners, and Resource Conservation Planners are contained in MassDEP's regulations 310 CMR 50.00. MassDEP held a public comment period and three hearings during the month of August 2007 on the certification requirements and is in the process of issuing final regulations.